Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov/)

Components of Participating Organizations
National Institute of Child Health and Human Development (NICHD), (http://www.nichd.nih.gov/)
Trans-NIH Zebrafish Coordinating Committee (TZCC), (http://www.nih.gov/science/models/zebrafish/)
National Cancer Institute (NCI), (http://www.nci.nih.gov/)
National Center for Research Resources (NCRR), (http://www.ncrr.nih.gov/)
National Eye Institute (NEI), (http://www.nei.nih.gov/)
National Heart, Lung, and Blood Institute (NHLBI), (http://www.nhlbi.nih.gov)
National Institute on Aging (NIA), (http://www.nia.nih.gov/)
National Institute on Alcohol Abuse and Alcoholism (NIAAA), (http://www.niaaa.nih.gov/)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), (http://www.niams.nih.gov/)
National Institute on Deafness and Other Communication Disorders (NIDCD), (http://www.nidcd.nih.gov/)
National Institute of Dental and Craniofacial Research (NIDCR), (http://www.nidcr.nih.gov/)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (http://www.niddk.nih.gov/)
National Institute on Drug Abuse (NIDA), (http://www.nida.nih.gov/)
National Institute of Environmental Health Sciences (NIEHS), (http://www.niehs.nih.gov/)
National Institute of General Medical Sciences (NIGMS), (http://www.nigms.nih.gov/)
National Institute of Mental Health (NIMH), (http://www.nimh.nih.gov/)
National Institute of Neurological Disorders and Stroke (NINDS), (http://www.ninds.nih.gov/)

Title: Tools for Zebrafish Research

Announcement Type
This is a reissue of PAR-02-142 which was previously released August 2, 2002.

Program Announcement (PA) Number: **PAR-05-080**

Catalog of Federal Domestic Assistance Number(s)
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Letters of Intent Receipt Date(s): August 19, 2005, 2006, 2007
Application Receipt Dates(s): September 19, 2005, 2006, 2007
Peer Review Date(s): February/March 2006, 2007, 2008
Council Review Date(s): May/June 2006, 2007, 2008
Earliest Anticipated Start Date: July 1, 2006, 2007, 2008
Additional Information To Be Available Date (Url Activation Date): March 21, 2005
Expiration Date: September 20, 2007

Due Dates for E.O. 12372
Not Applicable

Additional Overview Content

Executive Summary

- This Program Announcement (PA) encourages investigator-initiated applications designed to exploit the power of the zebrafish as a vertebrate model for biomedical and behavior research. Applications are welcome proposing to develop new tools or genetic or genomic resources of high priority to the zebrafish community that will advance the detection

and characterization of genes, pathways, and phenotypes of interest in development and aging, organ formation, behavior, sensory processing, physiological processes, and disease processes. This effort stems from an NIH initiative developed by the Institutes and Centers of the Trans-NIH Zebrafish Coordinating Committee (TZCC) under the co-chairmanship of NICHD and NIDDK.

- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the numbers, quality, duration, and costs of the applications received.
- This PA will use the NIH individual research project grant (R01) award mechanism.
- Eligible organizations include for-profit or non-profit organizations; public or private institutions, such as universities, colleges, hospitals, and laboratories; units or State and local government; eligible agencies of the Federal government; and, domestic or foreign institutions.
- Eligible principal investigators include any individual with the skills, knowledge, and resources necessary to carry out the proposed research. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.
- An individual principal investigator may submit only one application per year in response to this announcement. There is no limit to the number of different applications that an applicant institution may submit.
- Applications must be prepared using the most recent version of the PHS 398 research grant application instructions and forms available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: Grantsinfo@nih.gov.
- A complete listing of programmatic contacts for the TZCC Institutes and Centers can be found at http://www.nichd.nih.gov/PA/Zebrafish/ProgrammaticContacts.htm.
- A complete listing of grants management contacts for the TZCC Institutes and Centers can be found at http://www.nichd.nih.gov/PA/Zebrafish/GrantsManagement/Contacts.htm.
- Telecommunications for the hearing impaired is available at: TTY 301-451-0088

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Purpose

This Program Announcement (PA) is to encourage investigator-initiated applications designed to exploit the power of the zebrafish as a vertebrate model for biomedical and behavior research. Applications proposing to develop new tools or genetic or genomic resources of high priority to the zebrafish community that will advance the detection and characterization of genes, pathways, and phenotypes of interest in development and aging, organ formation, behavior, and disease processes are welcome. This effort stems from an NIH initiative developed by the Institutes and Centers of the Trans-NIH Zebrafish Coordinating Committee (TZCC; http://www.nih.gov/science/models/zebrafish/) under the co-chairmanship of NICHD and NIDDK. Since its formation in 1997, the committee has played an active role as an advocate for the zebrafish as an important model for development and disease research. PAR-02-142, “Tools for Genetic Studies in Zebrafish” (http://grants.nih.gov/grants/guide/pa-files/PAR-02-142.html) was issued in August 2002 because it was clear that there was a critical need for non-hypothesis driven, tool development proposals to be reviewed as a group, within a single framework. It focused on identifying additional mutants and developing new genetic tools in zebrafish. Ongoing dialog with the zebrafish research community, most recently at the Sixth International Meeting on Zebrafish Development and Genetics in June 2004, suggested a continuing need for not only tools, but high priority resources as well. Therefore, this PA is a continuation of the program initiated by PAR-02-142. The objective is to continue to broaden the range, power, and utility of tools for biomedical and behavioral research using zebrafish, and to develop genetic and genomic resources of high priority to the zebrafish community. Methodology developed and data and mutants generated as a result of this PA are expected to be made widely available to the research community as described by NIH Grants Policy (Principles and Guidelines for Recipients of NIH Research Grants and contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999, http://ott.od.nih.gov/NewPages/Rtguide_final.html and the NIH Model Organism Sharing Policy, http://grants.nih.gov/grants/policy/model_organism/index.htm).

Objectives to be addressed in applications submitted in response to this PA include, but are not limited to, the following:

- Development and/or application of novel methods of mutagenesis (e.g., insertional, site-specific, conditional knockout vectors or systems).
- Development of techniques supporting more efficient targeting of induced local lesions in genomes (TILLING).

- Development of technologies for gene inactivation and for gene expression manipulation including, but not limited to, morpholino oligonucleotides, new types of antisense technology, techniques for homologous recombination, techniques for gene trapping, and strategies for directing gene misexpression, or other transgenic methodologies.
- Development of high throughput small molecule screens.
- Development of new genetic or genomic resources that are of high priority for the zebrafish community.
- Development and/or application of novel screens for mutants. These may be Refinement of phenotypic analyses preparatory to screening, or phenotypic screens based on observation of alterations in morphology, physiology, or behavior;
- Screens focusing on identifying novel developmental genes and pathways, including those mediating sensitivity or resistance to environmental teratogens;
- Screens to analyze the genetic basis of adult phenotypes including behavior, aging, organ disease, cancer, and responses to environmental toxicants, alcohol, and drugs of abuse.

Interests of Participating Institutes and Centers

The participating NIH Institutes and Centers have provided a brief outline of their interests as they relate to the goals of this PA. These brief mission statements are intended to indicate the breadth of the biomedical areas of interest in which zebrafish are likely to be a useful model.

NCI: Generation and study of zebrafish models to identify and place genes in functional pathways that effect growth and development, in particular, genes/pathways that, when altered, result in uncontrolled or cancerous growth.

NCRR: The NCRR supports research projects that broaden the utility of the zebrafish model for cross-cutting biomedical research that is not encompassed within a single NIH Institute or Center. Interests include, but are not limited to, development of new methods for mutagenesis and/or phenotypic characterization that would be of use in research on a wide range of diseases or organs, particularly if these methods could be applied to other animal models as well as the zebrafish.

NEI: Research on the normal and abnormal visual system, including eye development, optic nerve guidance and the visual centers of the brain. This research might include the use of mutants to elucidate the cellular and molecular processes that control normal eye development and function and to provide models for the investigation of the genetic bases of inherited eye diseases.

NHLBI: Cellular and molecular functions of zebrafish genes that have potential to model human cardiovascular, blood, and pulmonary, or sleep disorders. Genetic basis of disorders of cardiovascular development and function; effect of mutations on subsequent organ development leading to such disorders as arrhythmia, cardiac hypertrophy, dilated cardiomyopathy, and heart failure; developmental aspects of endothelial dysfunction as the basis for vascular disorders; developmental defects in hematopoiesis and the relationship to disorders of the hematopoietic system; genetic basis of angiogenesis, and vasculogenesis; and, the genetic basis, regulation, and role of biological clock mechanisms in development and circadian behavior.

NIA: Basic research on the genetic and molecular basis of aging and longevity. Generation and analysis of late-onset disease models or long-lived mutants that can be used to identify, clone, and characterize genes involved in normal and pathological aging. Cellular and molecular function of genes expressed, for example, in the aging nervous system, cardiovascular, immune, and musculoskeletal systems. Such genes include, but are not limited to, those involved in neurodegenerative disorders, neuroplasticity, cell death, damage and repair of DNA and proteins, oxidative stress, and maintenance of differentiated cell function.

NIAAA: Mechanistic studies of ethanol-induced teratogenesis, behavioral impairments, and organ damage. These studies may include screening methods for alcohol-related phenotypes, gene identification, and functional analyses of these genes.

NIAMS: Mutations that have the potential to illuminate the development and function of the vertebrate musculoskeletal system and skin. The musculoskeletal system includes muscle, bone, articulated joints, cartilage, tendon, and ligament. Priority will be given to the establishment of collaborations between investigators with expertise in the zebrafish and investigators with expertise in the musculoskeletal systems and skin of mammals and humans.

NICHD: Identification, cloning, and characterization of the genes important in normal development as well as those mutant genes that cause developmental defects. Elucidation of the cellular, biochemical, molecular, and genetic mechanisms underlying normal and defective development. This includes, but is not limited to, the study of general mechanisms of pattern formation and cell lineage, neural crest development, cell specification, differentiation, migration, and fate in early development of many organs/systems such as limb, nervous system, immune system, and heart.

NIDCD: Identification and cloning of genes/proteins involved in the normal and disordered development in the areas of hearing, balance, smell, taste, voice, speech, and language. Elucidation of the cellular, molecular, and biochemical and sensory processing mechanisms governing the proliferative, regenerative, lineage determination, and developmental capacities of these sensory cells and tissues.

NIDCR: All aspects of normal and abnormal craniofacial development, including genetics, complex origins of craniofacial disorders, cell lineages and differentiation, cell signaling and gene regulation, embryonic patterning, imaging, biomimetics, and new technologies for high-throughput genetic and protein screens.

NIDDK: Research on diabetes, particularly studies on pancreatic beta cell function and development, obesity and mechanisms underlying satiety, other endocrine and metabolic diseases, hematologic disorders, physiology and diseases of the digestive system, liver, kidney, and urinary tract. Studies aiming to clarify the cellular and molecular events that dictate tissue and organ formation in all these systems are considered of relevance. In addition, studies that exploit the zebrafish to model physiological processes such as renal function, fluid and electrolyte balance, are relevant to NIDDK. These studies could include, but need not be limited to, studies to develop cell lines from any of the tissues or organs of interest, studies to characterize normal or abnormal function of tissues or organs of interest, methods to screen and identify additional mutations in these systems, and studies to define the molecular mechanisms that dictate cell-specific gene expression in relevant cell types.

NIDA: Identification of mechanisms underlying tolerance, sensitization, and addiction to drugs of abuse such as nicotine, amphetamine, cocaine, opiates, barbiturates, and hallucinogens. Identification of genetic suppressors and enhancers of the teratological effects of drugs of abuse on behavior and the nervous system. Processes involved in the development of brain regions and neurotransmitter systems mediating the hedonic and addictive properties of drugs of abuse.

NIEHS: Studies to examine the mechanism whereby environmental factors/agents alter any aspect of development. This includes the screening for mutants that ameliorate the toxicity of environmental agents, and the subsequent identification and characterization of the genes and pathways involved in their action. Characterization of the interactions among genetics, environmental agents, and time during development that lead to structural or functional abnormalities. Studies to examine the mechanistic pathways involved in developmental exposure to environmental agents and subsequent increased susceptibility to adult onset disease (developmental imprinting). Development of a mechanistically based model for testing environmental agents for developmental toxicity.

NIGMS: Development of novel methods for mutagenesis and manipulation of gene expression. Mutagenesis screens to identify and characterize genes that control fundamental biological mechanisms such as those that underlie gene regulation, chromosome organization and mechanics, cell growth and differentiation, pattern formation, sex determination, morphogenesis, cell cycle control, and behavior. Small molecule screens for phenotypes that are relevant to those fundamental biological mechanisms.

NIMH: Investigations that examine molecular, cellular, and biochemical bases of genetic mutations affecting neurogenesis, biological rhythms, learning, memory, and other cognitive functions and behaviors of the nervous system. These studies include, but are not limited to, development of screening methods for such mutations, identification, isolation, mapping, and functional analyses of the genes underlying mutations.

NINDS: Research on the development, normal function, and diseases of the nervous system. This research might include the use of mutants to understand the mechanisms controlling the following processes: neurogenesis, nervous system patterning, cell lineage, cell migration, formation of neural circuits, programmed cell death, axon pathfinding and regeneration, myelination, and motor and sensory function. In addition, the utility of mutants as models for neurodegenerative diseases for use in translational research, including therapeutic drug screens, functional neuroanatomy of the developing and adult nervous system, and use of optical imaging techniques to visualize neural activity, is of particular interest. The areas of interest listed above are not presented in any order of priority, they are only examples of areas of research to consider. Applications representing areas of interest to more than one Institute or Center will be assigned to multiple Institutes or Centers for funding consideration. Applicants are encouraged to propose work in other areas that are related to the objectives and scope of this PA.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the NIH Individual Research Project Grant (R01) award mechanism(s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise follow the instructions for non-modular research grant applications.

2. Funds Available

- There is no special set aside of funds for applications submitted in response to this announcement.
- The anticipated start dates for new awards will be July 1, 2006, 2007, and 2008.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Foreign Institutions
- Domestic Institutions

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

An individual principal investigator may submit one application in response to this PA per cycle.

2. Cost Sharing or Matching

Cost sharing is not required.

The most current Grants Policy Statement can be found at:
http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing.

3. Other-Special Eligibility Criteria

Not applicable

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below (Section IV.3.A). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Letters of Intent Receipt Date(s): August 19, 2005, 2006, 2007
Application Receipt Dates(s): September 19, 2005, 2006, 2007
Peer Review Date(s): February/March 2006, 2007, 2008
Council Review Date(s): May/June 2006, 2007, 2008
Earliest Anticipated Start Date: July 1, 2006, 2007, 2008

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Dr. Lorette Javois
Center for Developmental Biology and Perinatal Medicine
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 4B01, MSC 7510
Bethesda, MD 20892-7510
Rockville MD 20852 (for express/courier service; non-USPS service)
Telephone: (301) 496-5541
FAX: (301) 480-0303
Email: lj89j@nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above (Section IV.3.A.). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by CSR and responsiveness by the Trans-NIH Zebrafish Coordinating Committee.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm (see also Section VI.3. Reporting).

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.

6. Other Submission Requirements

Specific Instructions for Modular Grant applications.

Applications requesting up to $250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular budgets. Applicants must use the currently approved version of the PHS 398. Additional information on modular budgets is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

Specific Instructions for Applications Requesting $500,000 (direct costs) or More per Year.

Applicants requesting $500,000 or more in direct costs for any year must carry out the following steps:

1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The data sharing policy is available at http://grants.nih.gov/grants/policy/data_sharing. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, http://grants.nih.gov/grants/funding/2590/2590.htm). See Section VI.3. Reporting.

The Zebrafish International Resource Center (ZIRC) at the University of Oregon (http://zfin.org/zirc/home/stckctr.php), with its associated Zebrafish Information Network database (ZFIN, http://zfin.org/cgi-bin/webdriver?MIval=aa-labview.apg&OID=ZDB-LAB-991005-53), is the focal point for sharing of resources among investigators using zebrafish. Plans to share materials generated by projects under this PA through ZIRC, including but not limited to mutant fish, embryos, and sperm, genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains, should include evidence/documentation of coordination with staff at the Resource. A reasonable time frame for periodic deposition of mutants, sperm, reagents, and data should be specified in the application and will be considered during the review of the plan for sharing.

Applicants also are required to include a plan addressing if, or how, they will exercise their intellectual property rights while making available to the broader scientific community patentable research resources. The plan should address the following questions:

- Will material transfers be made with no more restrictive terms than in the Simple Letter MTA or the UBMTA?
- Will there be reach-through requirements on materials transferred?
- Should any intellectual property arise that requires a patent, will the technology remain widely available to the research community?

Applicants are reminded that the grantee institution is required to disclose each subject invention to NIH within two months after the inventor discloses it in writing to grantee institutional personnel responsible for patent matters. The awarding Institute reserves the right to monitor awardee activity in this area to ascertain if patents or patent applications on zebrafish identified through phenotypic screens and on phenotypic and genotypic data for all zebrafish strains or other patentable subject matter are adversely affecting the goals of the PA.

The plans for sharing research data, for sharing research resources, and for addressing intellectual property rights should be described in a brief section of the application immediately following the Research Plan. The section addressing these plans is limited to three pages in length and does not count as part of the 25 page limitation for the research plan.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines.

Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique
- Receive a second level of review by the appropriate national advisory council or board

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities
- Adequacy of plans to make widely available to the research community in a timely manner all research resources developed during the project
- Adequacy of plans to exercise (or not exercise) intellectual property rights while permitting wide availability to the research community of patentable research resources developed during the project

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The presence of a data sharing plan will be part of the terms and conditions of the award. The funding organization will be responsible for monitoring the data sharing policy.

2.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr and http://ott.od.nih.gov/newpages/rtguide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See Section VI.3. Reporting.

3. Anticipated Announcement and Award Dates

Not applicable

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document.

Summary statements of scored applications will be transmitted to the applicant by postal, e-mail, or other electronic means according to the individual institute or center's policy. If a grantee is not email enabled, a hard copy of the Notice of Grant Award will be mailed to the business official. Summary statements of unscored applications will be mailed to the applicants.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also Section IV.5. Funding Restrictions.

2. Administrative and National Policy Requirements

The final versions of the data and research resource sharing plans negotiated by NIH program Staff and the applicant will become a condition of the award of the grant.

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (http://grants.nih.gov/grants/funding/2590/2590.htm) and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Dr. Lorette Javois
Center for Developmental Biology and Perinatal Medicine
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 4B01, MSC 7510
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service; non-USPS service)
Telephone: (301) 496-5541
FAX: (301) 480-0303
Email: lj89j@nih.gov

A complete listing of programmatic contacts for the TZCC Institutes and Centers can be found at http://www.nichd.nih.gov/PA/Zebrafish/ProgrammaticContacts.htm.

2. Peer Review Contacts:

Dr. Alexandra Ainsztein
Cell Structure Function
Center for Scientific Review
6701 Rockledge Drive, Room 5144
Bethesda, MD 20892-7840
Bethesda, MD 20817 (for express/courier service; non-USPS service)
Telephone: (301) 451-3848

FAX: (301) 480-1988
Email: ainsztea@mail.nih.gov

3. Financial or Grants Management Contacts:

A complete listing of grants management contacts for the TZCC Institutes and Centers can be found at http://www.nichd.nih.gov/PA/Zebrafish/GrantsManagement/Contacts.htm.

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Public Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health
and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892